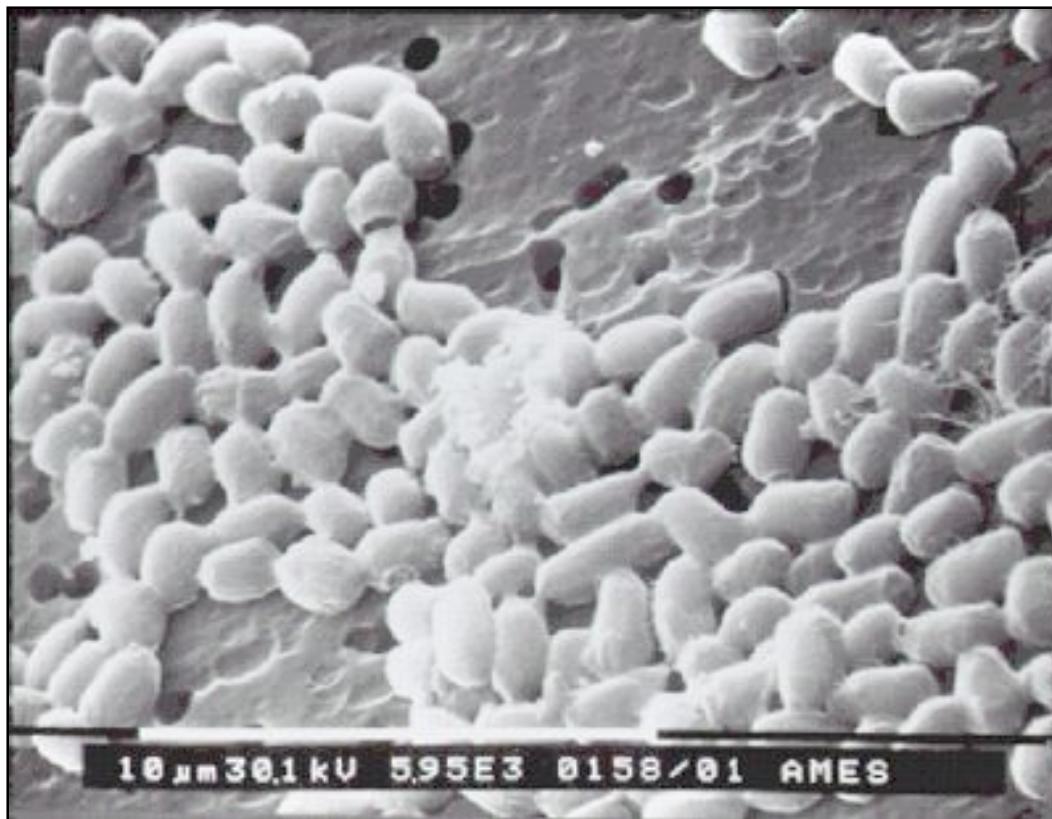


Regulating Biological Agents: Balancing Security and Bio- Medical Research



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Overview

- Why Congress tightened bio-agent rules
- Key legislation
- Who's in charge of bio-agent regulation
- Criteria for bio-agent controls
- Impacts on academic & public health labs
- Impacts on public health priorities
- Conclusions
- Policy alternatives and recommendations

Why Have Biological Agents Become a Big Deal?

- **1996 mail order plague – Larry Wayne Harris**
 - “Do it Yourself” approach to plague research
 - Led to new law on transfer/use of bio-agents
- **2001 anthrax mailed to politicians & media**
 - Triggered massive ongoing investigation
 - Led to new laws on possession of bio-agents
 - Military labs implicated as possible source for agents

Legislation – Biological-agents

- **Antiterrorism & Effective Death Penalty Act of 1996**
 - Governs transfer and use of bio-agents
- **USA PATRIOT Act of 2001**
 - Prohibits restricted persons from lab work
- **Public Health Security & Bio-terrorism Preparedness Response Act of 2002**
 - Governs bio-agent possession, lab security, bio-safety, training, inspections and notifications.

Why Did Congress Increase Regulation of Biological Agents?

- **Assumption 1:** Increased lab security will reduce improper use of bio-agents for terrorism.
- **Assumption 2:** Increased inventory controls will allow for rapid tracking of misused bio-agents.
- **Assumption 3:** Security clearances for lab workers handling bio-agents minimizes risks of their misuse.

Were The Assumptions Congress Made Correct?

- **Alternative Hypothesis 1:** Increased lab security may have no impact on improper use of bio-agents for terrorism.
- **Alt. Hypothesis 2:** Increased inventory controls of reproducible bio-agents doesn't guarantee misused bio-agents can be tracked.
- **Alt. Hypothesis 3:** Security clearances for lab workers may discourage legitimate scientists from pursuing bio-agent work.

Who's in Charge of Select Biological Agent Work?

- Responsibility depends on the Issue
- Who's in charge varies by issue.
- Multiple federal Laws govern laboratory work.



Select Agent Regulatory Issues:

Who Governs What?

 = Pre 2001
 = Post 2001

Laboratory Issues	DOJ	ICE	CDC	GAO	FBI	DOT	DHS
Restricted Persons	●		●		●		●
Visa controls		●					●
Responsible Official	●		●	●			
Criminal Investigations	●			●	●		
Restricted Biologic Agents			●		●		●
Focus on Bio-agent Research			●		●		●
Monitor Sensitive Research	●		●		●	●	●
Transport Controls						●	
Laboratory Security	●		●	●	●		●
Security/Emergency Plans			●	●	●		●

Who's Affected by the Rules?

1,653 labs admit possessing select agents

But only 817 are expected to register

- Public health labs – 98 in Laboratory Response Network (LRN)
- Academic/non-profit labs – 344 affected.
- Commercial labs – 375 affected.



What will the new Rule Cost?

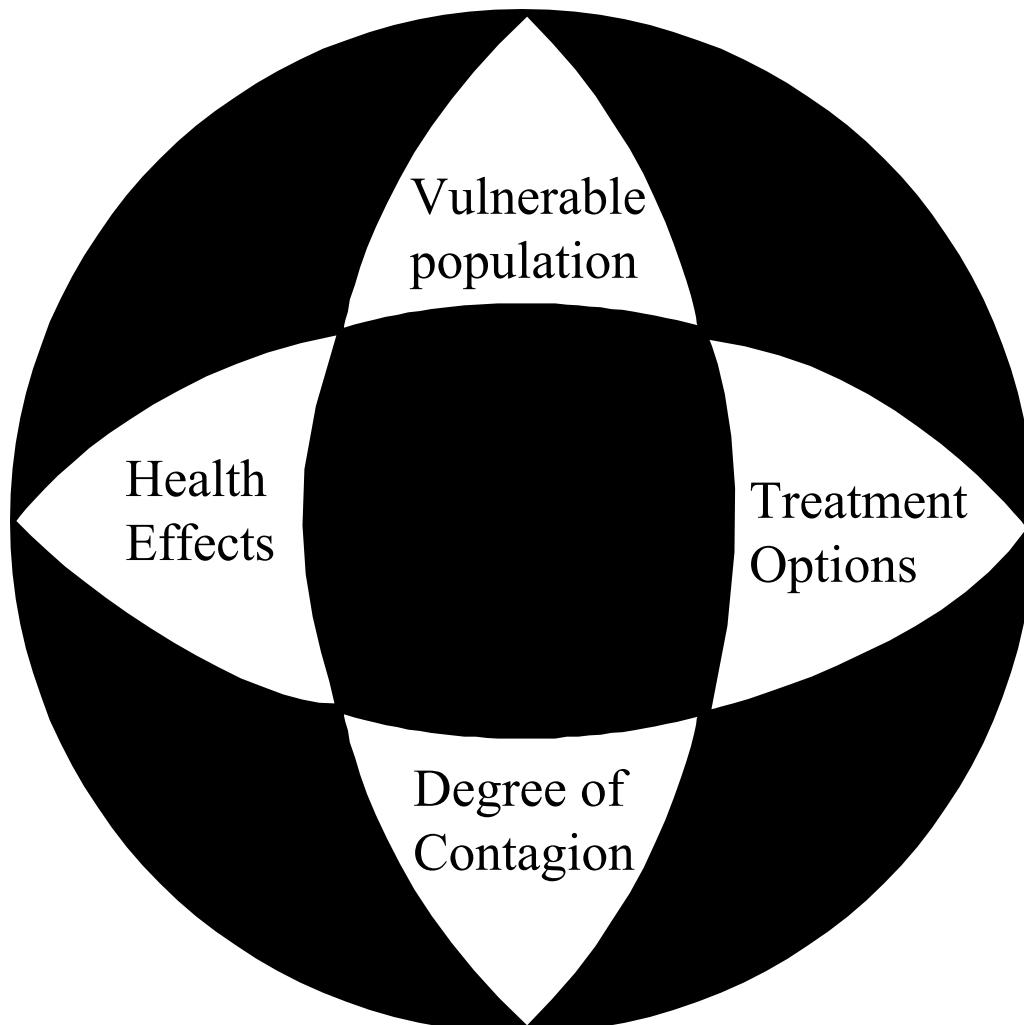
- **CDC grossly underestimates fiscal impacts**
 - Anticipates annualized costs of \$40 million
- **True costs are 3 to 5 times more expensive**
 - CDC estimates called “low ball” numbers
- **Rule doesn’t consider:**
 - Lost lab productivity
 - Increased capital investment costs
 - Lost opportunity costs
 - Lost students and researchers

“It isn’t the number of people killed. It is the potential of people getting killed.”

- Dr. Anthony Fauci, HHS, February 5, 2002
 - » Explaining why the Bush administration is providing an overwhelming increase in funds for bio-terrorism prevention.

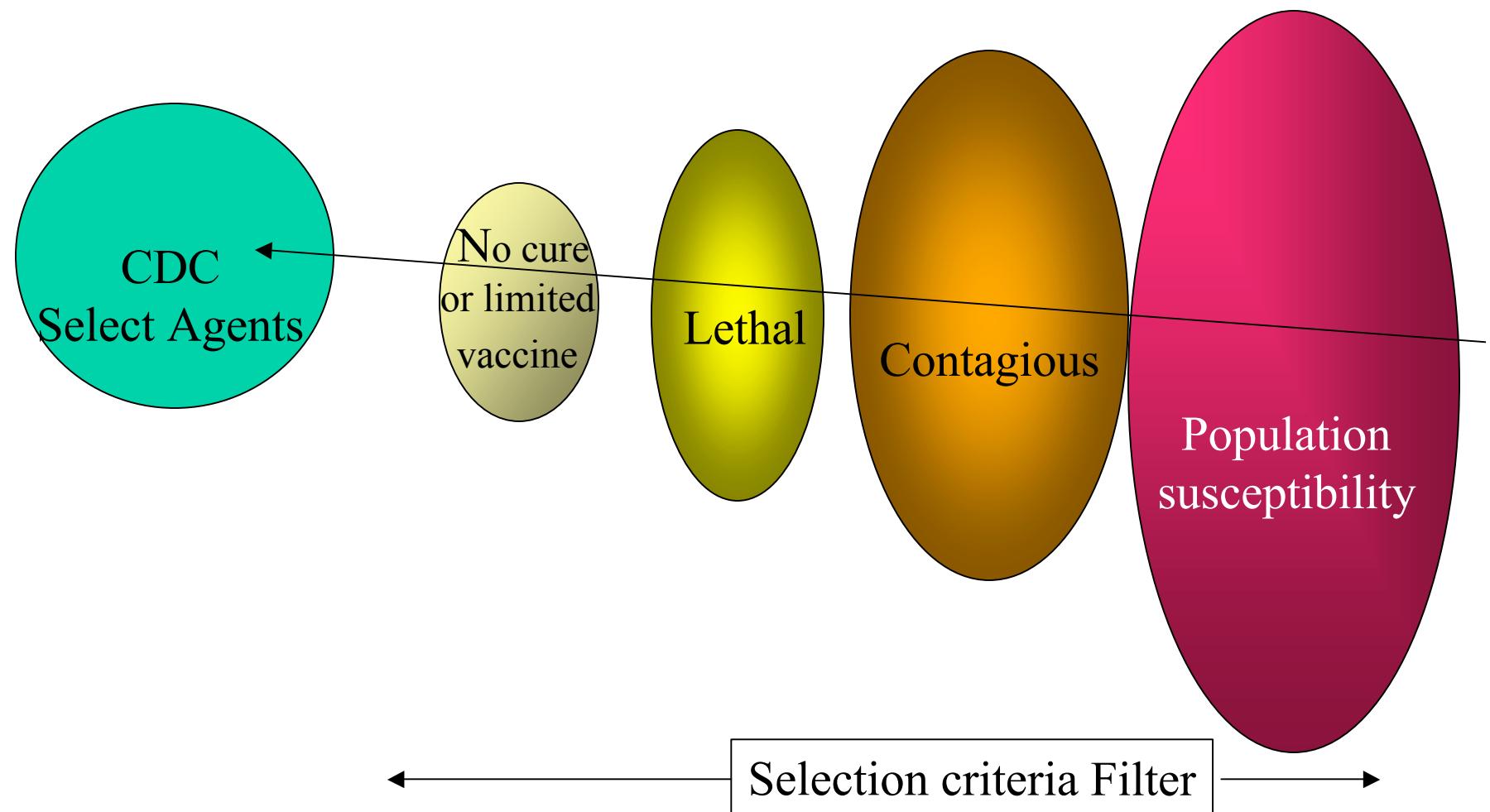
Step 1: Selecting Select Agents

Threshold Selection Criteria



Step 2: Selecting Select Agents

Applying Selection Criteria



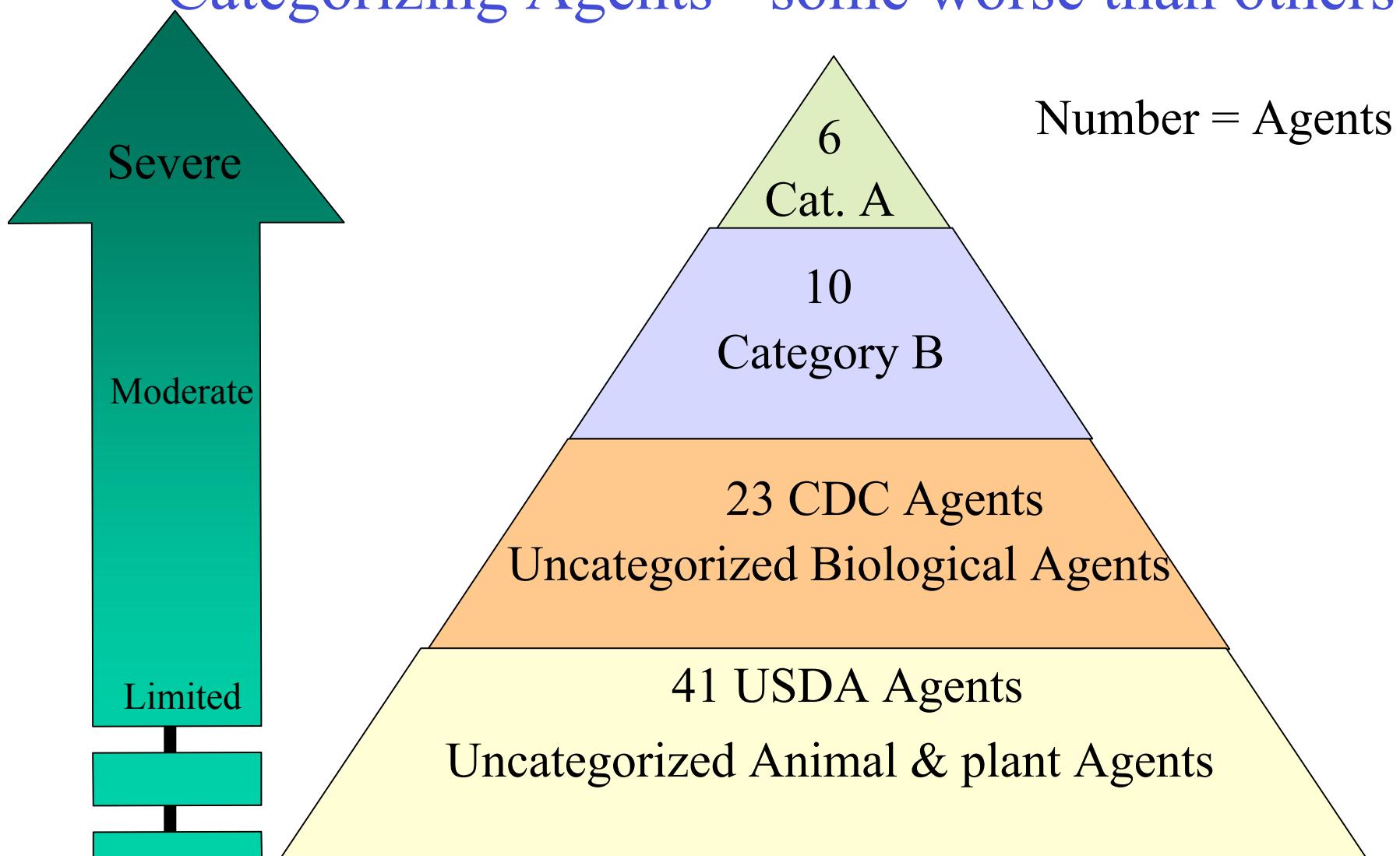
Step 2: Are Select Agents of Equal risk?

Risks vary by agent

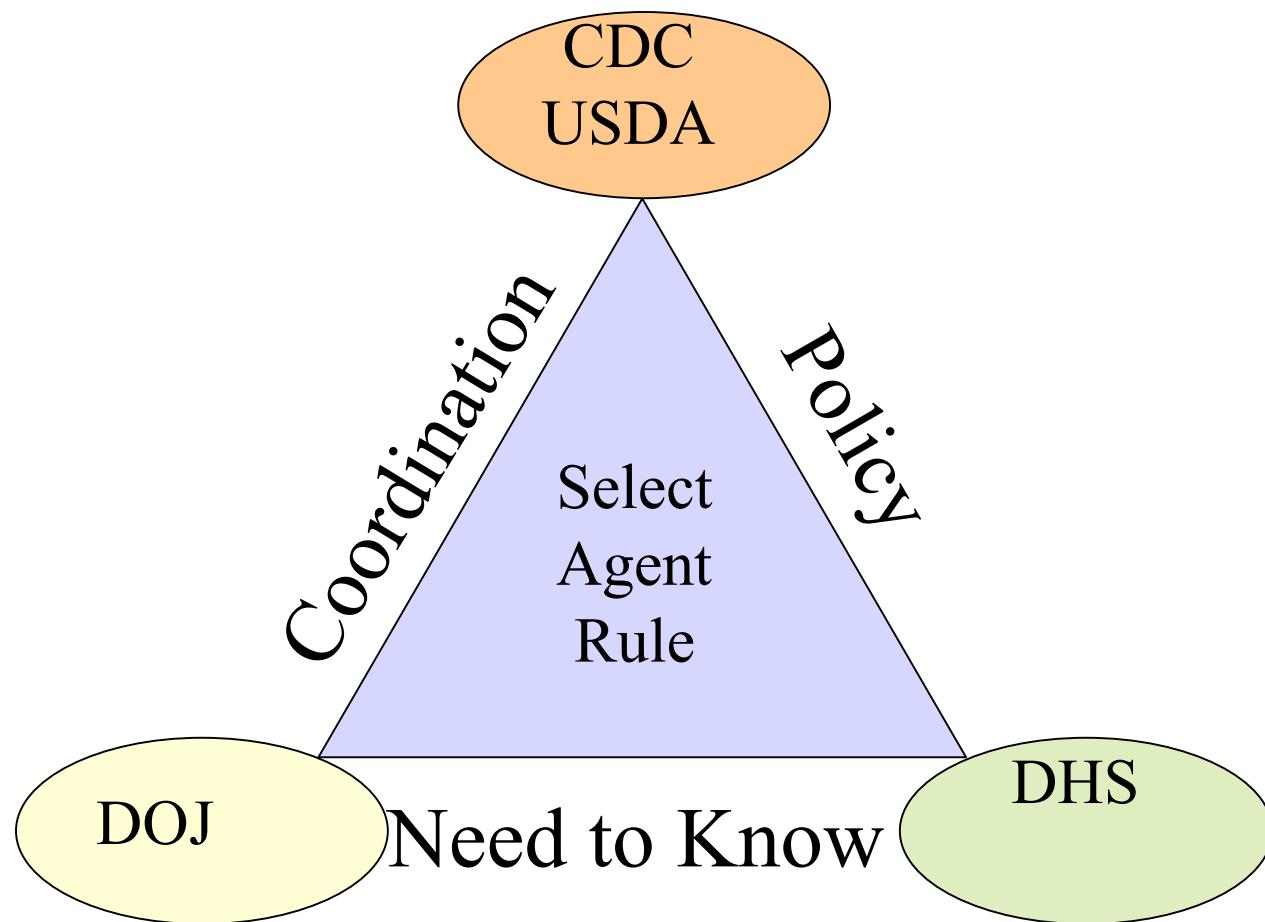
1. **Public Health Impacts** - Defined by high Morbidity and Mortality
2. **Dissemination Potential** – Defined by person to person transmissibility and potential for widespread production and distribution
3. **Special Public Health Preparation** - Such as stockpiling of vaccines, public education or surveillance and rapid diagnostic lab analysis
4. **Public Perception** – Agents that could cause mass fear and civil disruption.

Step 3: Priority Select Agents:

Categorizing Agents - some worse than others



Bio-Medical Research: Who in Government Controls this Work?



Select Agent Rule: Are Lab Requirements Excessive?

1. Registration for possession, use/transfer
 - Will labs admit possession?
2. Security Risk Assessment
 - Does it stop criminals? Will honest lab workers accept scrutiny?
3. Designation of a Responsible Person
 - Who will accept liability of being in charge?
4. Inventory Tracking and Controls
 - Bio-agents aren't pencils - can't be counted

Select Agent Rule: Are Lab Requirements Excessive?

(Continued)

6. Training and Inspections
 - What standards will be expected?
7. Notification of theft, loss or release
 - How can you tell if a theft has occurred?
8. Safety & Security Plans
 - Who decides if bio-safety and security is met?
9. Emergency Response Plan
 - Will community accept lab activities?

Do Lab Regulations Eliminate Link to Bio-Terrorism?



Would regulation
have prevented
earlier incidents?

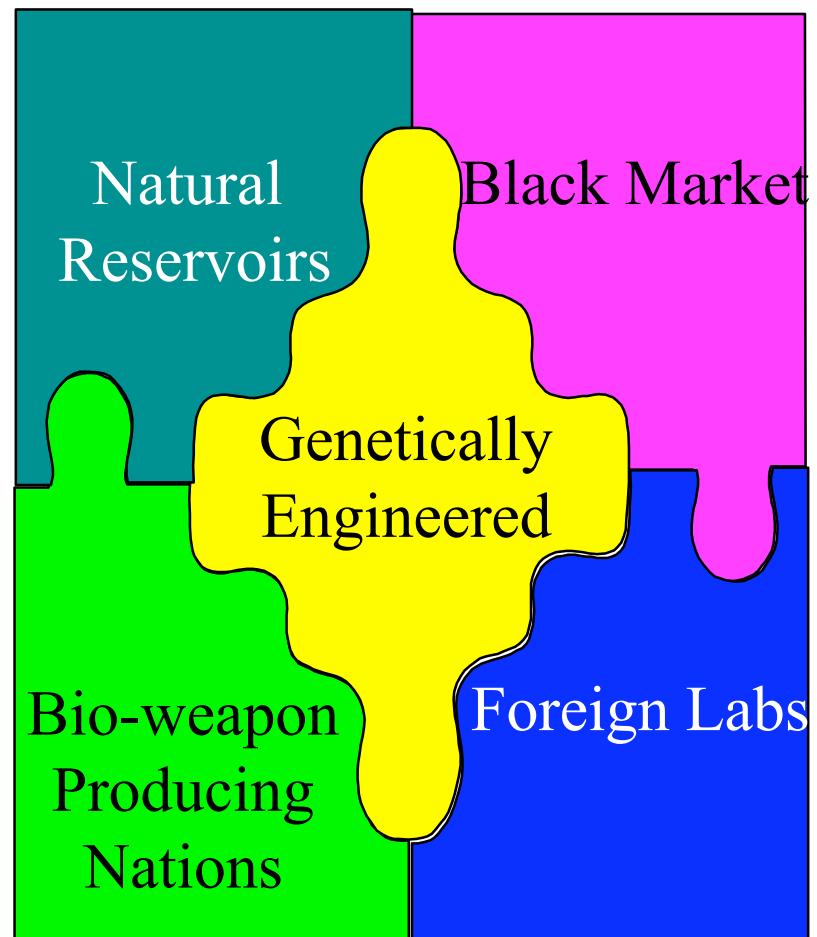
to Bio-agents

Bioterrorism

How long is arm of
Patriot Act? Does it
impact foreign labs?

What Other Sources Exist?

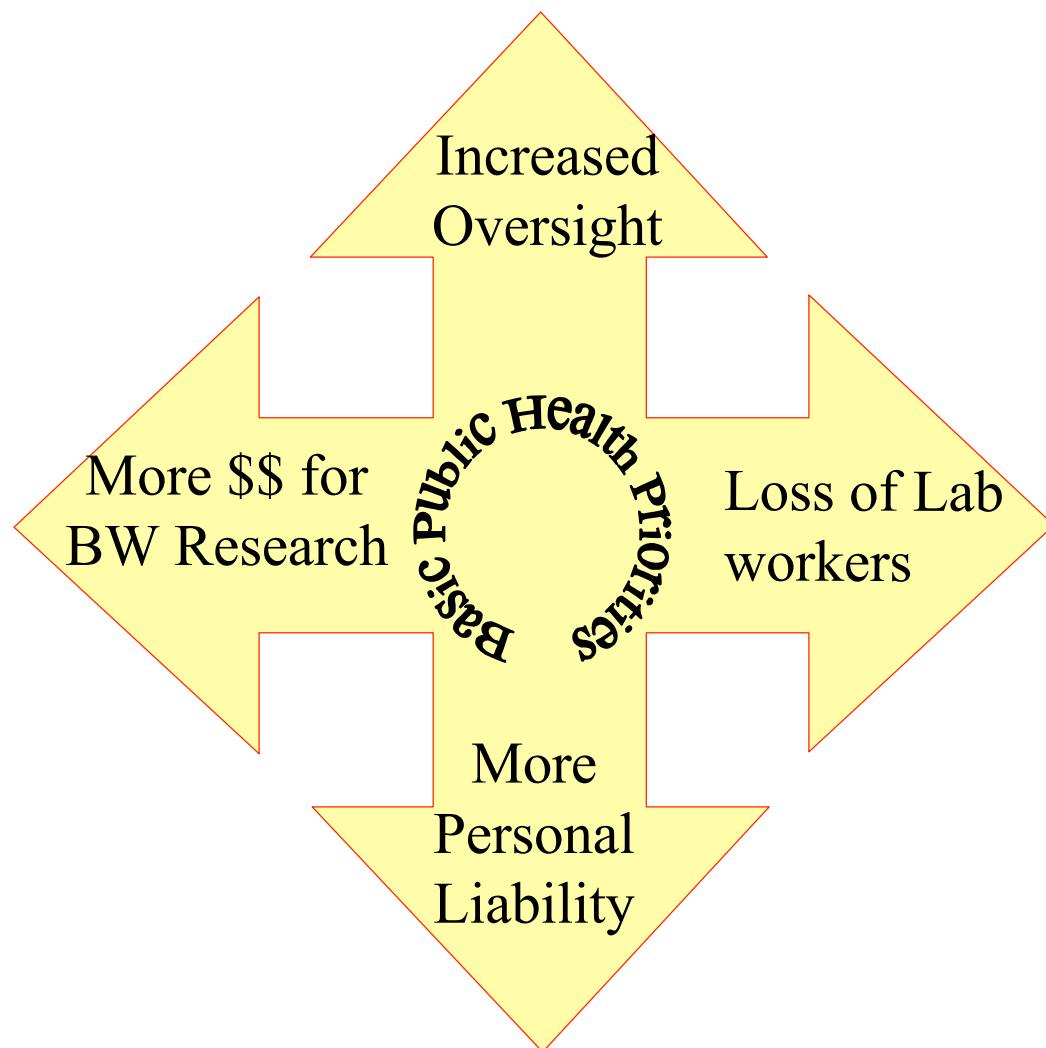
- Natural Reservoirs
 - For some easy access
- Black Market Sources
 - Terrorist group issues
- Foreign Labs
 - Not under Convention
- Bio-weapon Producers
 - Rogue nations
- Genetic Engineering
 - Limited controls exist



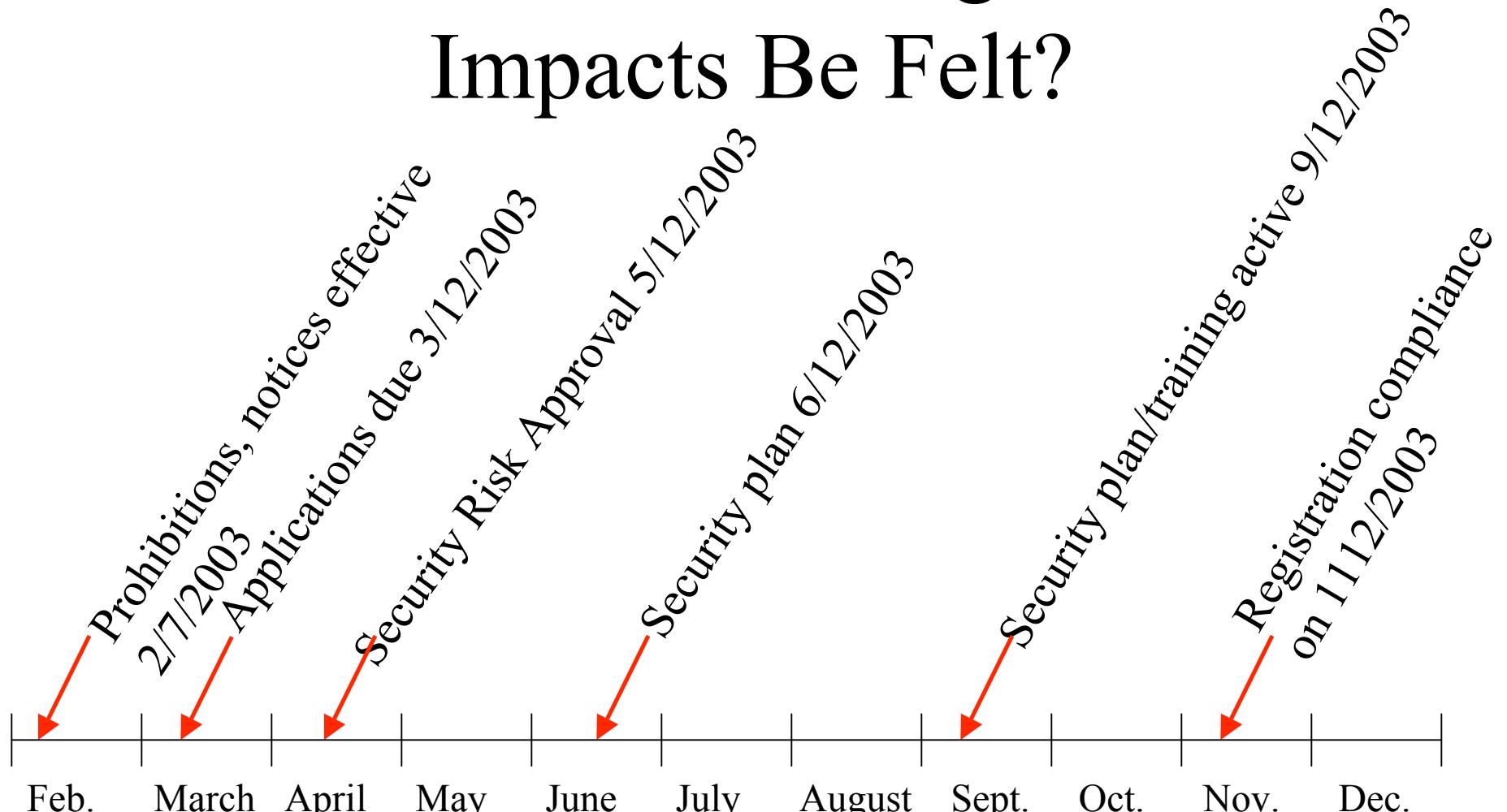
Do Lab Regulations Eliminate Link to Bio-Terrorism?



Impacts on Public Health Priorities: Competing Forces



When Will Select Agent Rule Impacts Be Felt?



Compliance timetable for 2003

New Lab Bio-Security Considerations

Risk Assessment Principles

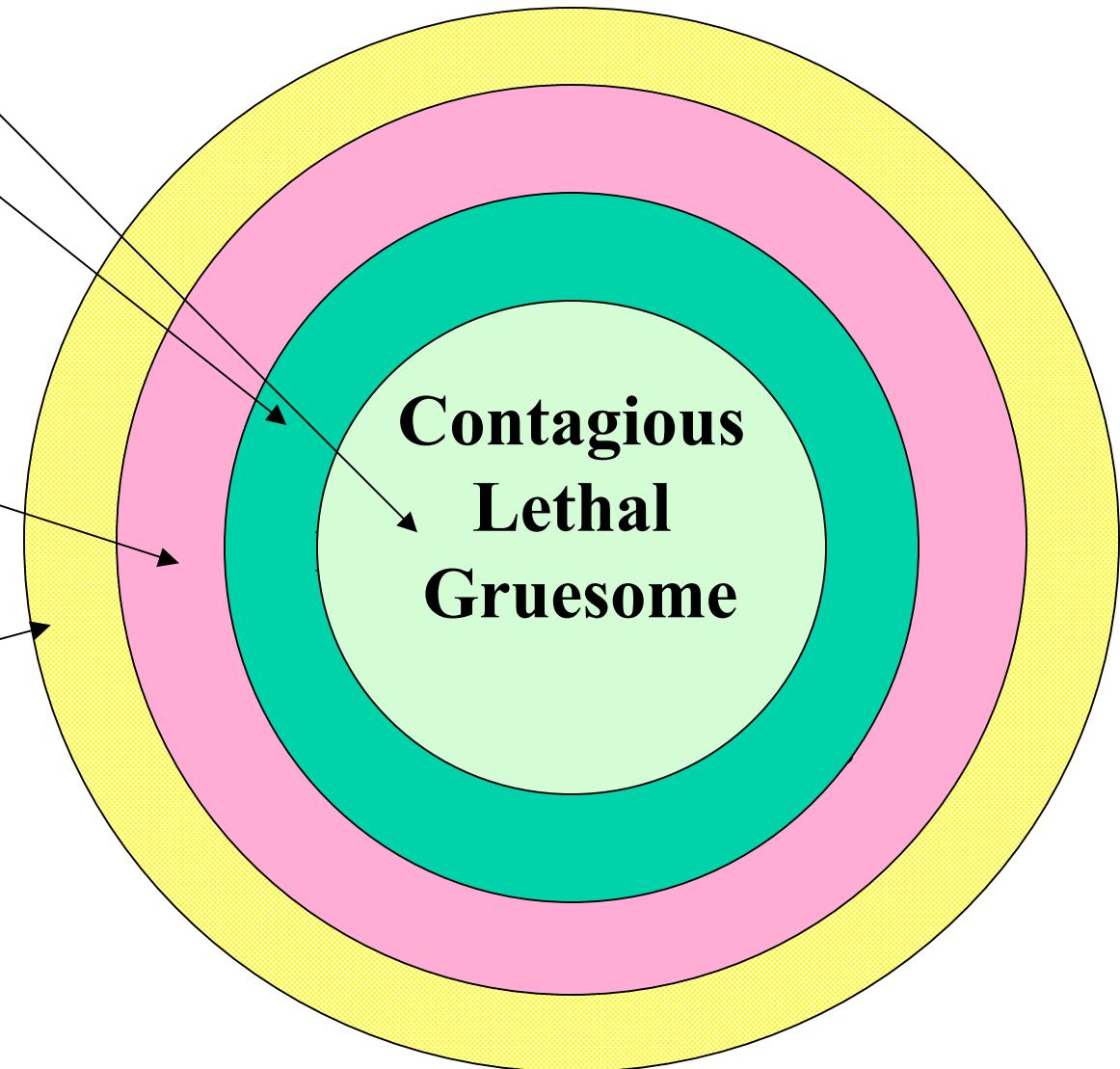
Public Perception Factors

Community Factors

Security Factors

Threat Assessment

**Contagious
Lethal
Gruesome**



Conclusions

Getting the Balance Right

- **Priorities:** Bio-medical research priorities affected by focus on BW agents.
- **Regulations:** Controls not commensurate with risks posed by academic/commercial labs
- **Funding:** Increased budgeting for security related public health measures.

Policy Recommendations

- **Minimize Burdens on Research**
 - Provide training support for academic labs
 - Adopt Performance based security concept
- **Involve Scientists in Decision making**
 - Create Select Agent research advisory committee
- **Minimize Individual Liabilities**
 - Provide due process protections
 - Establish an “Innocent researcher” defense
 - Don’t burden honest researcher